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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,777	04/09/2004	Glauco P. Tocchini-Valentini	911076.90023	1445

26710 7590 03/23/2011
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EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1635

NOTIFICATION DATE	DELIVERY MODE
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03/23/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No. 10/821,777	Applicant(s) TOCCHINI-VALENTINI ET AL.	
	Examiner DANA SHIN	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-23 is/are pending in the application.
- 4a) Of the above claim(s) 18-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1-27-2011</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on January 27, 2011.

Currently, claims 1 and 4-23 are pending in the instant application. Claims 18-23 have been withdrawn from further consideration as being drawn to non-elected inventions.

Accordingly, claims 1 and 4-17 are under examination on the merits in the instant case.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112, second paragraph

Claims 12-17 remain rejected under 35 U.S.C. 112, second paragraph as failing to particularly point out and distinctly claimed the subject matter for the reasons of record as set forth in the Office action mailed on October 4, 2010 and for the reasons stated below.

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Applicant's arguments filed on January 27, 2011 have been fully considered but they are not persuasive. Applicant argues that the claim amendments filed on January 27, 2011 are sufficient to overcome this rejection. Contrary to applicant's argument, the amendments filed on January 27, 2011 are not sufficient to comply with the second paragraph of 35 U.S.C. 112. In particular, it was indicated in the last Office action that claim 12 does not point out what constitutes the "second" RNA. Further, as currently amended, applicant has deleted the phrase "first RNA". As such, the claims 12-13 and 15-17 recite only a "second" RNA. Hence, the recitation of the "second" RNA without reciting a "first" RNA renders the claims indefinite. Further, as currently amended, claim 14, line 2 refers to "the first RNA molecule". However, claim 12 as currently amended does not recite such limitation. Hence, there is insufficient antecedent basis for this limitation in claim 14. Since the claim amendments have not fully cured the deficiencies and further created more issues as noted hereinabove, this rejection is maintained.

Claim Rejections - 35 USC § 112, first paragraph

Claims 1 and 4-17 remain rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement for the reasons of record as set forth in the Office action mailed on October 4, 2010 and for the reasons stated below.

Applicant's arguments filed on January 27, 2011 have been fully considered but they are not persuasive. Applicant argues that applicant is not required to disclose any species to satisfy the written description requirement. Applicant is correct only to the extent that a disclosure or enumeration of species is not required if the state of the art was sufficiently developed at the time

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of filing. That is, the specificities and the amount of "description" of the "claimed" invention depend on the level of skill and knowledge in the art (see factor "E" on page 5 of the last Office action) and the predictability in the art (see factor "F" on page 5 of the last Office action) as of the filing date sought by applicant. As explicitly acknowledged on the record by the declarant (see the declaration filed on January 19, 2010) and applicant (see the remarks filed on January 19, 2010), the claimed methods were "neither known, nor predictable" at the time of filing. See paragraphs 6 and 11 of the declaration and page 7 of the remarks filed on January 19, 2010. That is, it is clearly recorded that one would not have known how to practice the entire genus of the claimed methods without the description of the claimed methods in "full, clear, concise, and exact terms" in light of the declaration. Note that the first paragraph of 35 U.S.C. 112 requires that the specification "shall contain a written description of the invention" in "full, clear, concise, and exact terms" so as to allow any person skilled in the art to make and use the claimed invention.

Now, note that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a

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biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated.”). See also MPEP §2163.

Hence, in the instant case, given the expressly acknowledged and recorded “unpredictability” pertaining to the claimed invention, the instant specification must provide a sufficient description of a representative number of species having substantial variation. As indicated in the last Office action, the description disclosed in Figure 14 is not a sufficient number of species encompassed by the claimed genus. Further, as noted in the last Office action, there is no single disclosure showing the “actual reduction to practice” (see factor “A” on page 4 of the last Office action) for the claimed method steps.

For some reasons unknown to the examiner, applicant mentions “enablement” issues and “working examples”. See page 7 of the remarks: “35 USC §112, first paragraph requires nothing more than that the specification enables a person of ordinary skill in the art how to make and use the claimed invention...Applicants are not required to disclose even a single working example in order to enable an invention.” It appears that applicant thinks that the first paragraph of 35 U.S.C. is only for “enablement” requirement and excludes “written description” requirement. Alternatively, it appears that applicant is confused about the ground of instant rejection. First, note that the case laws cited by applicant are dated to 1970 and 1971. For applicant’s own edification, note that it has long been established in the patent law that enablement and written description requirements are two separate, independent requirements under 35 U.S.C. 112, first paragraph, and thus, the written description requirement is separate and distinct from the enablement requirement. See MPEP §2161. Second, the instant rejection is not an enablement

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rejection, but a written description rejection. Hence, applicant's arguments addressing enablement issues are irrelevant to the issues raised in the last Office action.

In addition, it is noted that applicant has pointed out two references (Di Segni et al. and Anderson et al.) published in the year of 2008, in order to support applicant's argument that "a skilled artisan would understand that cleavage of endogenous target mRNAs and cleavage of RNA molecules by eukaryotic tRNA endonucleases is possible" and perform the claimed methods "without undue experimentation." Again, applicant's attention is directed to the fact that the instant rejection is not an enablement rejection, and as such, the issue of "undue experimentation" is not relevant to the instant rejection. Further, note that the purpose of written description requirement is "to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him." In re Edwards, 568 F.2d 1349, 1351-52, 196 USPQ 465, 467 (CCPA 1978). (emphasis added). As such, the 2008 publications pointed out by applicant do not whatsoever show, let alone corroborate, that the inventors had possession of the claimed methods "as of the filing date of the application relied on".

Applicant asserts that the result shown in Figure 3 of the instant specification is "predictive of further experiments". As such, applicant has acknowledged on the record that the instant specification fails to satisfy "actual reduction to practice" (see factor "A" on page 4 of the last Office action). That is, the instant specification makes it clear that the inventors were not in possession of the genus of the claimed methods at the time of filing. Note that the purpose of the written description requirement is "to ensure that the inventor had possession, as of the filing

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date of the application relied on, of the specific subject matter later claimed by him.” In re Edwards, 568 F.2d 1349, 1351-52, 196 USPQ 465, 467 (CCPA 1978). (emphasis added).

Applicant contends that the claims do not need to recite “various details or factors which must be presumed to be within the level of ordinary skill in the art.”, thus, applicant argues that providing the description for the claimed invention “is not necessary for one of skill in this field.” It is noted that applicant’s contentions and arguments that the claimed invention “must be presumed to be within the level of ordinary skill in the art” are in stark contrast to the declaratory statements specifically pointing out that the claimed invention could not have been “presumed to be within the level of ordinary skill in the art” since it “was not known or at all predictable” at the time of filing, and since the prior art “does not immediately implicate that the skilled person could form an active trans-formed structure and predict that an eukaryal endonuclease would subsequently cleave the trans-formed structure.” See paragraphs 6 and 8 of the declaration filed on January 19, 2010. See also paragraph 8, which specifically states that “it was not until 2001 that my group started to consider trans-formed structures and non-tRNA molecules as substrates for eukaryal endonucleases”. Hence, applicant's arguments/contentions that the claimed invention was “within the level of ordinary skill in the art” contradict the statements made by the declarant, who made the declaratory statements under Section 1001, Title 18 of the U.S.C. See paragraph 12 of the declaration.

In view of the foregoing, it is concluded that the instant specification does not convey with reasonable clarity to those skilled in the art that the inventors were in possession of and invented the claimed genus as of the earliest filing date sought in the instant case. Hence, this rejection is maintained.

Conclusion

No claim is allowed.

This application contains claims 18-23 drawn to inventions nonelected without traverse in the reply filed on March 8, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamita can be reached on 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1635

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